



[Billing Code: 4120-01-P]

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3363-N]**

#### **Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—August 22, 2018**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, August 22, 2018. This meeting will focus on the state of evidence on Chimeric Antigen Receptor (CAR) T-cell therapies that are approved by the Food and Drug Administration (FDA). We are seeking the MEDCAC's recommendations regarding collection of patient reported outcomes (PRO) in cancer clinical studies. The MEDCAC will specifically focus on appraisal of evidence-based PRO assessments to provide information that impacts patients, their providers, and caregivers after a CAR T-cell therapy intervention for the patient's cancer. This meeting is open to the public in accordance with the Federal Advisory Committee Act.

**DATES:** Meeting Date: The public meeting will be held on Wednesday, August 22, 2018 from 7:30 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5:00 p.m., EDT, Monday, July 16, 2018. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EDT on Monday, July 16, 2018.

Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5:00 p.m. EDT, Wednesday, August 15, 2018.

We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EDT Friday, August 3, 2018.

**ADDRESSES:** Meeting Location: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov) or by regular mail to the contact listed in the

**FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at [Maria.Ellis@cms.hhs.gov](mailto:Maria.Ellis@cms.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MCAC, see the MEDCAC Charter (<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf>) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC* (<http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10>)).

## **II. Meeting Topic and Format**

This notice announces the Wednesday, August 22, 2018, public meeting of the Committee. This meeting will focus on the state of evidence on CAR-T cell therapies that are approved by the FDA. We are seeking the MEDCAC's recommendations regarding collection of PRO in cancer clinical studies. The MEDCAC will specifically focus on appraisal of evidence-based PRO assessments to provide information that impacts patients, their providers, and caregivers after a CAR T-cell therapy intervention for the patient's cancer. Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS website no later than 2 business days before the meeting. We encourage the participation of organizations with expertise in the appraisal of the state of evidence for patient reported outcomes, development of patient reported health outcome measures, and use of patient reported health outcome assessments in cancer clinical trials. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 23, 2018. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the

meeting will be available on the following web site prior to the meeting:

[http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-](http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&)

[index.aspx?bc=BAAAAAAAAAAAA&](http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&). We require that you declare at the meeting

whether you have any financial involvement with manufacturers (or their competitors) of

any items or services being discussed. Speakers presenting at the MEDCAC meeting

should include a full disclosure slide as their second slide in their presentation for

financial interests (for example, type of financial association - consultant, research

support, advisory board, and an indication of level, such as minor association < \$10,000

or major association > \$10,000) as well as intellectual conflicts of interest (for example,

involvement in a federal or nonfederal advisory committee that has discussed the issue)

that may pertain in any way to the subject of this meeting. If you are representing an

organization, we require that you also disclose conflict of interest information for that

organization. If you do not have a PowerPoint presentation, you will need to present the

full disclosure information requested previously at the beginning of your statement to the

Committee.

The Committee will deliberate openly on the topics under consideration.

Interested persons may observe the deliberations, but the Committee will not hear further

comments during this time except at the request of the chairperson. The Committee will

also allow a 15-minute unscheduled open public session for any attendee to address

issues specific to the topics under consideration. At the conclusion of the day, the

members will vote and the Committee will make its recommendation(s) to CMS.

### III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), fax number, and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

### IV. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at <http://www.dhs.gov/real-id-enforcement-brief>. We recommend that confirmed registrants arrive reasonably early,

but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

## **V. Collection of Information**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

**Authority:** 5 U.S.C. App. 2, section 10(a).

Dated: June 4, 2018

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**Kate Goodrich**

Director, Center for Clinical Standards and Quality,

Chief Medical Officer,

Centers for Medicare & Medicaid Services.

[FR Doc. 2018-12831 Filed: 6/14/2018 8:45 am; Publication Date: 6/15/2018]